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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/506,729	09/03/2004	Andrew Stocker	100664-1P US	4896

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EXAMINER

BARKER, MICHAEL P

ART UNIT	PAPER NUMBER
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1626

DATE MAILED: 03/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/506,729	STOCKER ET AL.	
	Examiner	Art Unit	
	Michael P. Barker	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 March 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) 1 and 6-12 (in part); 2,3,5 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 6-12 (in part); 4 is/are rejected.
- 7) ☒ Claim(s) 1 and 6-12 (in part); 2,3,5 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>3/24/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-12 are pending in this application. Group I, **Claims 1** and **6-12** (in part), as well as **Claim 4**, is rejected under 35 U.S.C. 102(e). Group II, **Claims 1** and **6-12** (in part), as well as **Claims 2-3** and **5**, is withdrawn as being drawn to nonelected subject matter.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on March 24, 2005 was correctly filed. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement was considered by the examiner. Please refer to Applicant's PTO-1449 submitted herewith.

Priority

This application, filed September 3, 2004, is a 371 of PCT/GB03/00924, filed March 4, 2003, and claims foreign priority to UK Application No. 0205175.3, filed March 6, 2002.

Response to Restriction

Applicants election without traverse of Group I, **Claims 1** and **6-12** (in part), as well as **Claim 4**, drawn to compounds and compositions of the general Formula (I), wherein **B** is phenyl, is acknowledged. Applicant dutifully pointed out Examiner's error in the restriction requirement regarding Group II. Group II should have been drawn to compounds and compositions of the general Formula (I), wherein **B** is *heterocycle*.

The restriction requirement is deemed proper and is hereby made final, and **Claims 1** and **6-12** (in part), as well as **Claims 2-3** and **5** are withdrawn from further consideration. Group I was examined on the merits and is not free of prior art thereby giving rise to the rejection that follows.

Claim Rejections - 35 USC § 102

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1 and 6-12 (in part), as well as **Claim 4** are rejected under 35 U.S.C. 102(e) as being anticipated by WIPO Publication No. 2002034718 A1 (hereinafter "Horvath, et al."), published May 2, 2002, filed October 15, 2001, and having priority to October 24, 2000. Specifically, Horvath, et al. discloses the compound 6-hydroxy-1H-indole-carboxylic acid 1,2-diphenylethylamide [Example 94 at p. 46; Registry Number 420136-85-2], which anticipates Applicant's Group I, wherein **B** is phenyl; **R¹** is H; **R⁴** is hydroxy; and **R¹⁴** is H.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 10-11 provide for the use of a compound of formula (I); but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process

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applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 10-11 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

To overcome this rejection, Applicants can reword **Claims 10-11**, for example, combining the language of **Claims 10-11**:

Claim 10: “A method for the treatment of disorders selected from the group consisting of type 2 diabetes, insulin resistance, syndrome X, hyperinsulinaemia, hyperglucagonaemia, cardiac ischaemia, and obesity, comprising administering a compound according to any one of claims 1 or 5 to a subject in need thereof.”

Objections

Claims 7-9 are objected to as being substantial duplicates of **Claim 1**. Specifically, **Claims 7-9** recite, “A compound of formula (I), or a pharmaceutically acceptable salt or in-vivo hydrolysable ester thereof. . .” Following this language, in each claim, is an intended use, which is interpreted as having no patentable weight.

Group II, **Claims 1** and **6-12** (in part), as well as **Claims 2-3** and **5**, is objected to for being drawn to nonelected subject matter.

References Cited

If a copy of a provisional application listed on the bottom portion of the accompanying Notice of References Cited (PTO-892) form is not included with this Office action and the PTO-892 has been annotated to indicate the copy was not readily available, the copy could not be

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readily obtained when the Office action was mailed. Should Applicant desire a copy of such a provisional application, Applicant should promptly request the copy from the Office of Public Records (OPR) in accordance with 37 CFR 1.14(a)(1)(iv), paying the required fee under 37 CFR 1.19(b)(1). If a copy is ordered from OPR, the shortened statutory period for reply to this Office action will not be reset under MPEP § 710.06 unless Applicant can demonstrate a substantial delay by the Office in fulfilling the order for the copy of the provisional application. Where the applicant has been notified on the PTO-892 that a copy of the provisional application is not readily available, the provision of MPEP § 707.05(a) that a copy of the cited reference will be automatically furnished without charge does not apply.

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael P. Barker whose telephone number is (571) 272-4341. The examiner can normally be reached on Monday-Friday 8:00 AM- 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Joseph K. McKane, can be reached at (571) 272-0699. The unofficial fax phone for this group are (571) 273-8300.


When filing a FAX in Technology Center 1600, please indicate the Header (upper right) "Official" for papers that are to be entered into the file, and " Unofficial" for draft documents and other communications with the PTO that are not for entry into the file of the application. This will expedite processing of your papers.

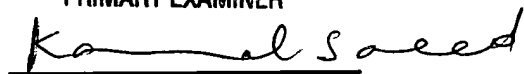
Communication via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by applicant and should be

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addressed to [joseph.mckane@uspto.gov]. All Internet e-mail communications will be made of record in the application file. PTO employees will not communicate with applicant via Internet e-mail where sensitive data will be exchanged or where there exists a possibility that sensitive data could be identified unless there is of record an express waiver of the confidentiality requirements under 35 U.S.C. 122 by the applicant. See the Interim Internet Usage Policy published by the Patent and Trademark Office Official Gazette on February 25, 1997 at 1195 OG 89.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is viable through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


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